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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,366	12/03/2003	Claudio Soto-Jara	009621-34567 DIV	8149

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EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 05/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary	Application No.	Applicant(s)	
	10/726,366	SOTO-JARA, CLAUDIO	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.O.O

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to an inhibitory peptide capable of inhibiting β pleated sheet formation in amyloid β-peptide, classified in class 530, subclass 350.

II. Claims 3-8, drawn to an inhibitory peptide capable of inhibiting conformational changes in prion PrP protein associated with amyloidosis, classified in class 530, subclass 300.

III. Claim 9, drawn to a peptide mimetic (PMiAβ5), classified in class 562, subclass 400.

IV. Claim 10, drawn to a peptide mimetic (PMiPrP13), classified in class 562, subclass 503.

V. Claim 11, drawn to a peptide mimetic (PMiPrP5), classified in class 562, subclass 507.

VI. Claim 12, drawn to a method for reducing the formation of amyloid or amyloid like deposits involving abnormal folding into β sheet structure of amyloid β peptide or for reducing the amount of said amyloid β peptide which has already formed into a beta sheet structure comprising bringing into the presence of said amyloid β peptide an effective amount of an inhibitory peptide, classified in class 514, subclass 2.

VII. Claim 13, drawn to a method for reducing the formation of amyloid or amyloid like deposits involving conformational changes in prion Pr protein or reducing the amount of said prion Pr protein which has already formed into amyloid or amyloid-like deposits comprising bringing into the presence of said prion Pr protein an effective amount of an inhibitory peptide, classified in class 514, subclass 2.

VIII. Claim 14, drawn to a method for reducing the formation of amyloid or amyloid like deposits by administration of a peptide mimetic, classified in class 514, subclass 553.

The inventions are distinct, each from the other because of the following reasons:

a. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-V are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Further, the peptides of Groups I and II can be prepared by processes which are materially different from the methods to prepare the peptide mimetics of Groups III-V. Additionally, each of Groups I-V can be used in materially different methods, such as in various diagnostic or therapeutic methods.

Furthermore, searching the inventions of Groups I-V would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications and separate search requirements. The amino acid searches and technical literature searches for the inventions of Groups I-V are no coextensive.

b. Inventions VI-VIII are unrelated. Inventions VI-VIII are different methods because they require different ingredients, process steps, and endpoints. Groups VI-VIII are different methods requiring different method steps, wherein each is not required, one for another. For example, Invention VI requires search and consideration of bringing into the presence of the amyloid β peptide prior to or after the abnormal folding into a β sheet structure an effective amount of an inhibitory peptide capable of inhibiting β pleated sheet formation in amyloid β peptide, which is not required by the other inventions. Invention VII requires search and consideration of bringing into the presence of a prion Pr protein prior to or after conformational changes into amyloid deposits an effective amount of an inhibitory peptide capable of inhibiting conformational changes in prion PrP protein associated with amyloidosis, which is not required by the other inventions. Invention VIII requires search and consideration of efficacy of therapy by

administration of a peptide mimetic to reduce the formation of amyloid or amyloid like deposits, which is not required by the other inventions.

Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups VI-VIII have a separate status in the art as shown by their different classifications and separate, non coextensive search requirements. As such, it would be burdensome to search the inventions of Groups VI-VIII together.

c. Inventions I and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as in various diagnostic procedures for screening or as a probe in immunoassays or immunochromatography.

d. Inventions II and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product claimed can be used in materially different processes, such as in various diagnostic procedures for screening or as a probe in immunoassays or immunochromatography.

e. Inventions III/IV/V and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products claimed can be used in materially different processes, such as in various diagnostic procedures for screening.

f. Inventions I and VII-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups I and VII-VIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VII-VIII do not recite the use or production of the inhibitory peptide capable of inhibiting β pleated sheet formation of Invention I.

g. Inventions II and VI and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups II and VI and VIII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI and VIII do not recite the use or production of the inhibitory peptide capable of inhibiting conformational changes in prion PrP protein of Invention II.

h. Inventions III/IV/V and VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions of Groups III/IV/V and VI and VII are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions VI and VII do not recite the use or production of the peptide mimetics of Inventions III/IV/V.

2. This application contains claims directed to the following patentably distinct species of the claimed invention:

A method for reducing formation of amyloid or amyloid like deposits by administering a peptide mimetic, wherein the peptide mimetic is selected from:

a. PMiAβ5

b. PMiPrP13

c. PMiPrP5

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 14 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If Applicant selects Invention VIII, one species of peptide mimetic must also be chosen to be fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (571) 272-0881. The examiner can normally be reached on 8:30-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BEB
Art Unit 1647
16 May 2005

Bridget E. Bunner
patent examiner